Atty. Docket No. 07189.0014.DVUS02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Joseph S. Podolski	Title:	IMPROVED COMPOSITIONS FOR THE TREATMENT OF MALE ERECTILE DYSFUNCTION
App. No.:	10/700,274	Art Unit:	1616
Conf. No.:	9175	Examiner:	Pryor, Alton Nathaniel
Filing Date:	November 3, 2003		

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

I, Joseph S.Podolski, hereby declare and say as follows.

1. I am the President and Chief Executive Officer of Repros Therapeutics, Inc. (the "Company") and have been since 1992.

2. One of my responsibilities in my role with the Company is to supervise scientific experiments and clinical trials.

3. I am familiar with the subject matter and disclosure of the above-identified Patent Application, of which I am the named inventor.

4. Subsequent to filing U.S. Patent Application No. 09/154,677 from which the above-identified Patent Application claims priority, the Company conducted a study in an attempt to improve the multiple drug therapy of prostaglandin, papaverine and phentolamine (hereinafter, "Trimix") for the treatment of moderate to severe erectile dysfunction. Data are provided in attached Appendix A.

5. The study consisted of randomized, double-blind intracavernosal injection of one of the following four treatment solutions into 40 human male patients with severe erectile dysfunction for whom the highest approved dosage of Caverject® (20 μg alprostadil) was ineffective. After an initial in-office Caverject® injection (Visit 1), patients received one dose of

the following blinded treatments each week: (i) Treatment 1 (0.5 ml of a solution containing 5.0 mg/ml phentolamine mesylate; 0.01 mg/ml alprostadil; 0.35 mg/ml L-arginine) (ii) Treatment 2 (0.5 ml of a solution containing 5.0 mg/ml phentolamine mesylate; 0.04 mg/ml alprostadil; 0.35 mg/ml L-arginine; (iii) Treatment 3 (0.5 ml of a solution containing 7.5 mg papaverine HCl, 5.0 mg/ml phentolamine mesylate; 0.005 mg/ml alprostadil; 0.35 mg/ml L-arginine); (iv) Treatment 4 (0.5 ml of a solution containing 30 mg/ml papaverine HCl; 5.0 mg/ml phentolamine mesylate; 0.010 mg/ml alprostadil; 0.35 mg/ml L-arginine).

6. The number of patients receiving full erections from the 65 test subjects and the representative percentage efficacy for each of the treatment solutions was as follows: Caverject (Visit 1) – 0%; (i) Treatment 1 – 43%; (ii) Treatment 2 – 46%; (iii) Treatment 3 – 46%; and (iv) Treatment 4 – 51%.

7. Comparing the results of Treatments 1 and 4 indicated that patients with severe erectile dysfunction may be treated equally well with intracavernosal injections of either Bimix (alprostadil and phentolamine) or Trimix (alprostadil and phentolamine and papaverine) formulation comprising L-arginine.

8. I further declare that all statements made herein are based on my knowledge and are true, and further that these statements were made with the knowledge that willful, false statements and the like are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and such willful, false statements may jeopardize the validity of any patents issued from the patent application.

11/19/09

Date

Joseph S. Podolski

Appendix A

Table 1. Treatment combinations received during study

	Bimix 1	Bimix 2	Trimix 3	Trimix 4
Alprostadil	0.010 mg/ml	0.040 mg/ml	0.005 mg/ml	0.010 mg/ml
Phentolamine mesylate	5 mg/ml	5 mg/ml	5 mg/ml	5 mg/ml
Papaverine HCl	0	0	7.5 mg/ml	30 mg/ml
L-arginine	0.35 mg/ml	0.35 mg/ml	0.35 mg/ml	0.35 mg/ml
Glycine	7.5 mg/ml	7.5 mg/ml	7.5 mg/ml	7.5 mg/ml
Mannitol	24 mg/ml	24 mg/ml	24 mg/ml	24 mg/ml
Benzyl alcohol	8.4 mg/ml	8.4 mg/ml	8.4 mg/ml	8.4 mg/ml
Final pH	4.01	4.01	4.01	4.01

Table 2. Results of study

Treatment	Erectile Response Rate (%)	Incidence of Penile Pain (%)
Caverject® (visit 1)	0	41
Bimix 1	43	28
Bimix 2	46	43
Trimix 3	46	19
Trimix 4	51	28